IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF UTAH

CENTRAL DIVISION

BASIC RESEARCH, LLC, et al., Plaintiffs, vs. FEDERAL TRADE COMMISSION and THE UNITED STATES OF AMERICA, Defendants.	**MEMORANDUM DECISION AND ORDER** Case No. 2:09-cv-0779 CW *Consolidated with* Case No. 2:09-cv-972

INTRODUCTION

At issue in this case are advertising claims Basic Research[1] makes for two of its products—Akävar and Relacore. The Federal Trade Commission (the "FTC") contends the advertising claims violate a Decision and Order it entered on June 19, 2006 (the "Agreement").[2] Before Basic Research can make representations about its products in advertisements, it must "possess and rely upon a reasonable basis for the representation, which shall consist of competent and reliable scientific

[1] "Basic Research" collectively refers to Plaintiffs Basic Research, LLC and its affiliates Sovage Dermalogic Laboratories, LLC, The Carter-Reed Company, LLC, and Dynakor Pharmacal, LLC, as well as A.G. Waterhouse, LLC, Dennis Gay, and Mitchell K. Friedlander.

[2] The Decision and Order reflects the terms of a settlement agreement between Basic Research and the FTC that was memorialized in an Agreement Containing Consent Order. Because the terms were negotiated and agreed upon, the court refers to the document as the Agreement, although it is also a consent order or final order of the FTC.

evidence." Agreement, 4 (Dkt. No. 1, Ex. A). The parties dispute whether Basic Research has competent and reliable scientific evidence to support its advertising claims and have filed cross motions for summary judgment to resolve this issue. For the reasons discussed below, the court grants Basic Research's motion for summary judgment and denies the FTC's motion for summary judgment.

FACTUAL BACKGROUND

Akävar Background and FTC Challenges

The FTC contends that Basic Research violated the Agreement by making false statements about Akävar in its advertising. Akävar is a compound that contains Yerbé Mate, Guarana, and Damiana (the "Herbal Compound") as well as other active ingredients. It is a dietary supplement that purportedly helps with weight loss by suppressing appetite. The FTC contends that Basic Research made the following claims about Akävar and that such claims are not supported by competent and reliable scientific evidence:[3]

> [1] Akävar users can eat all they want and still lose weight;
>
> [2] Akävar automatically restricts caloric intake with no will power required on the part of users to limit their food or caloric intake;
>
> [3] The Andersen/Fogh study proves that Akävar users can eat all they want and still lose weight;
>
> [4] The Andersen/Fogh study proves that Akävar causes substantial weight loss;
>
> [5] The Andersen/Fogh study proves that Akävar causes weight loss for virtually all users; and

[3] Basic Research disputes the FTC's characterization of its advertising claims.

> [6] The Andersen/Fogh study proves that Akävar automatically restricts caloric intake with no will power required on the part of users to limit food intake.

FTC Mem. in Supp. Mot. for Partial Sum. J., at 5 (Dkt. No. 64).

The Andersen/Fogh study was a double-blind, placebo controlled, peer-reviewed, published study conducted in 2001 by two researchers, which Basic Research relied on to support its advertising claims. Under the study, researchers used four different modules to determine whether the Herbal Compound[4] may aid in weight loss. *See* T. Andersen & J. Fogh, *Weight Loss and Delayed Gastric Emptying Following a South Am. Herbal Preparation in Overweight Patients*, J. HUM NUTR. DIETET, 243–50 (2001) (Dkt. No. 88, Toubro Disc. Ex. 5-1) (hereinafter "Andersen/Fogh study"). One module had seven volunteers take the Herbal Compound with apple juice. The researchers tested the rate of gastric emptying. The researchers then tested the same volunteers to determine the rate of gastric emptying when the volunteers took a placebo. The researchers found a statistically significant slower rate of gastric emptying when the volunteers took the Herbal Compound. *Id.* at 247. The implications of this are that a person will feel fuller longer and therefore decrease one's caloric intake. *Id.* at 249.

The second module looked at the effect on body weight after test subjects took the Herbal Compound for ten days. Those taking the Herbal Compound lost more weight, but the weight loss differences between those taking the Herbal Compound and those taking the placebo could have been explained by an "eventual laxative effect" of the Herbal Compound. Søren Toubro M.D.,

[4] Unlike Akävar, the capsules used in the Andersen/Fogh study contained no other active ingredients than the Herbal Compound.

Review of a South Am. Herbal Preparation, at 2 (Dkt. No. 88, Toubro Disc. Ex. 5-3) (Mar. 9, 2007) (hereinafter "Toubro Rev.").

The third module involved forty-seven test subjects, who were overweight. They either took the Herbal Compound (twenty-four subjects), or a placebo (twenty-three subjects) before each main meal for forty-five days. Andersen/Fogh Study, at 246 (Dkt. No. 88, Toubro Disc. Ex. 5-1). The study did not specify how many meals a test subject had to consume each day. *See id.* Test subjects were asked, however, "not to change their dietary habits, and were not asked to make any dietary records since this would have influenced their behavior." *Id.* at 249. The study found the mean weight loss for those taking the Herbal Compound was significant when compared to those who only took the placebo. *Id.* at 248–49. Of the twenty-four subjects who took the Herbal Compound, all but one experienced weight loss ranging from 2.2 kg to 13.2 kg. over the forty-five day period. *See* Raw Data for Andersen/Fogh Study, at 1 (Dkt. No. 88, Toubro Disc. Ex. 5-2). The researchers stated the results "suggest[] that the effect on gastric emptying was sufficient to influence food energy intake." Andersen/Fogh Study, at 249 (Dkt. No. 88, Toubro Disc. Ex. 5-1).

In other words, because the Herbal Compound appeared to have "delayed gastric emptying [and] reduced the time to perceived gastric fullness," test subjects naturally decreased their food intake even when they had been told not to vary it. *Id.*

The fourth module monitored certain test subjects for 12-months in an uncontrolled setting where they were given no instructions about their eating. The test subjects in this last group had successfully lost weight in the 45-day study, and continued to take the Herbal Compound for 12-months. The researchers found the test subjects neither lost nor gained any additional weight during that 12-month period, which showed the Herbal Compound also may be effective for weight

maintenance. *Id.*

In 2006, Basic Research asked Søren Toubro, M.D. to review the Anderson/Fogh study. Dr. Toubro is "an internationally recognized authority on obesity and various medical conditions associated with obesity, including the long-term dietary and pharmaceutical treatment of obesity." Supplemental Declaration of Dr. Søren Toubro, M.D., ¶ 2 (Sept. 10, 2012) (Dkt. No. 88, Ex. B) (hereinafter "Toubro Supp. Decl."). Dr. Toubro completed a written review on March 9, 2007, and informed Basic Research that the study was well designed. Toubro Rev., at 2 (Dkt. No. 88, Toubro Disc. Ex. 5-3). This fact was further corroborated by Frank Greenway, M.D. in 2008. Dr. Greenway is the "Medical Director and Professor at Pennington Biomedical Research Center, Louisiana State University." *Id.* ¶ 32. By letter, Dr. Greenway stated his "opinion is congruent with that of Dr. Toubro," because the Andersen/Fogh Study "had valid study designs that should allow one to rely upon the results that were reported in the article." Greenway Lttr., at 2 (Jan. 23, 2008) (Dkt. No. 88, Toubro Disc. Ex. 5-4).

Approximately two years later, Dr. Toubro reviewed the Andersen/Fogh Study again, along with other studies and sources that were similar in nature. After completing his review, Dr. Toubro concluded that the advertising claims for Akävar were supported by competent and reliable scientific evidence. Declaration of Søren Toubro, M.D., ¶ 28 (Feb. 8, 2010) (Dkt. No. 88, Ex. B, Attach. 3) (hereinafter "Toubro Decl.").

In 2012, Dr. Toubro provided a supplemental declaration. He was asked to assume that Basic Research had made the advertising claims the FTC alleges above. Basic Research further asked Dr. Toubro to apply the standard set forth in the court's June 1, 2012 Order when reviewing the evidence Basic Research relied on to make its advertising claims. He again concluded that the Andersen/Fogh

study provides a reasonable basis for Basic Research's advertising claims, and that subsequent studies provide "further corroboration. Toubro Supp. Decl., ¶¶ 23–24 (Dkt. No. 88, Ex. B). Moreover, Dr. Toubro opined that the Andersen/Fogh study and the other reviews of that Study show "there is a causal connection between the Study and the representations made about Akävar." *Id.* ¶ 27.

Besides conducting his own review, Dr. Toubro also looked at a written opinion provided by George A. Bray, M.D. on April 27, 2009. (Dkt. No. 88, Toubro Disc. Ex. 5-16) (hereinafter "Bray Opinion"). "Dr. Bray is one of the most, if not the most, respected and distinguished expert in the field with more than 40 years of experience in obesity research." Toubro Supp. Decl., ¶ 30 (Dkt. No. 88, Ex. B). Dr. Bray had opined that the Andersen/Fogh Study supported Basic Research's advertising claims, and he stated the reasons for his opinion. Bray Opinion, 2–3 (Dkt. No. 88, Toubro Disc. Ex. 5-16); *see also* Declaration of Dr. George A. Bray, ¶ 28 (Oct. 19, 2009) (Dkt. No. 88, Toubro Disc. Ex. 5-17). Dr. Toubro found Dr. Bray's opinion, itself, to be competent and reliable scientific evidence. Toubro Supp. Decl., ¶ 33 (Dkt. No. 88, Ex. B).

In response to these opinions, the FTC offers the opinion Edward R. Blonz, who has a Ph.D. is nutrition. According to Dr. Blonz, the Andersen/Fogh study does not provide competent and reliable scientific evidence to support Basic Research's advertising claims. Initially, Dr. Blonz criticized the study for using lactose as the placebo and not including certain data, which "reflect[ed] negatively on the quality of this study." Expert Report & Declaration of Edward R. Blonz, Ph.D., at 21 (May 23, 2012) (Dkt. No. 65) (hereinafter "Blonz Rpt."). Later, however, Dr. Blonz acknowledged that "the competency and reliability of the [Andersen/Fogh] study as published research is not the issue." Supplemental Report & Declaration of Edward R. Blonz, Ph.D., ¶ 16 (Jan.

28, 2013) (Dkt. No. 99, Ex. 1) (hereinafter "Blonz Supp. Rpt."). Thus, there is no dispute that the Andersen/Fogh study is both competent and reliable scientific evidence.

Although Dr. Blonz acknowledges the Andersen/Fogh study is both competent and reliable, he nevertheless contends it does not support Basic Research's advertising claims due to a lack of correlation between what the study showed and what Basic Research claims. *See id.* ¶¶ 12–18. To draw this conclusion, Dr. Blonz compared Basic Research's evidence essentially to the "Gold Standard." Specifically, Dr. Blonz stated the following scientific assumption he applied in his first report:

> The *ideal* for support in scientific research is a clinically significant finding in a randomized double-blind, placebo-controlled, clinical study, with these results being published in a peer-reviewed scientific journal. Findings should be confirmed by additional investigations at independent research institutions. Support of this nature provides reliable findings that are free of bias introduced by either the subject or the researcher. . . .

Blonz Rpt., at 10 (Dkt. No. 65) (emphasis added). The following day, the FTC used the same standard to support its motion for partial summary judgment and stated "failure to comport with these elements disqualifies purported scientific support for a weight loss claim from being reliable and competent scientific evidence." FTC Mem. in Supp., at 8–9 (Dkt. No. 64).

One week later, the court issued its June 1, 2012 Order that interprets what constitutes a "reasonable basis" under the Agreement. The Order states there must be a causal connection between the evidence and the advertising claim. Order, ¶ 5 (June 1, 2012) (Dkt. No. 69). Additionally, the evidence must be competent and reliable, which can be shown by various factors. *Id.* Neither the Agreement nor the Order requires those factors to be an "ideal" study that would meet the Gold Standard. Yet, Dr. Blonz did not revise his report to apply the correct standard after

the Order issued, nor did the FTC modify its briefing to allow for the fact that a weight loss claim may still be supported by competent and reliable evidence even if the Gold Standard is not met.[5]

Besides applying the incorrect standard to measure whether Basic Research's evidence was competent and reliable, Dr. Blonz also used some incorrect facts to draw his conclusions. Dr. Blonz states that the "[m]ost significant" deficiency of using the Andersen/Fogh study to support Basic Research's advertising claims "relates to dose." Blonz Supp. Rpt., ¶ 13 (Dkt. No. 99, Ex. 1). Dr. Blonz asserts that when Akävar is taken as directed, it only provides "2/3 the amount of the YGD components used in the AF study," and is thus "a fraction of the amount administered in [the study]." *Id.* ¶¶ 13–14.

Two capsules of Akävar equal one dose. The amount of the Herbal Compound in the two capsules is the exact amount administered in the Andersen/Fogh study before each main meal. Second Supplemental Declaration of Dr. Søren Toubro, M.D., ¶ 10 & n.6 (Mar. 22, 2013) (Dkt. No. 119) (hereinafter "Toubro Second Supp. Decl."). Initially, however, Basic Research informed consumers "not to exceed four capsules a day." Declaration of Ronald F. Price, ¶ 8 (Mar. 29, 2013) (Dkt. No. 118) (hereinafter "Price Decl."). That only allowed consumers to take Akävar before two main meals. Consequently, Dr. Blonz asserts that the Akävar dose is lower than the dose in the Andersen/Fogh study and therefore the study cannot support Basic Research's advertising claims. Yet, the Andersen/Fogh study did not specify that it had to be taken before *three* meals. It only stated it had to be taken before *main* meals. Because the number of meals was not specified, it is

[5] The FTC discussed the court's order in its combined opposition and reply memorandum, but it did not address that its expert had applied an incorrect standard and how that may have impacted his analysis and conclusions.

incorrect to assume that each study participant had three main meals a day. *See* Toubro Second Supp. Decl., ¶¶ 12–13 (Dkt. No. 119).

Moreover, in June 2008, Basic Research modified Akävar's dosage instruction to state, "[t]ake two capsules with a full glass of water before main meals." Price Decl., ¶ 8 (Dkt. No. 118). Thus, at least since 2008, Akävar's dosage instructions match the dosage instructions used in the Andersen/Fogh study. Toubro Second Supp. Decl., ¶¶ 11, 14 (Dkt. No. 119). Neither Dr. Blonz nor the FTC account for this in their conclusions despite dosage being the "most significant" deficiency according to Dr. Blonz.

Dr. Blonz also asserts the Andersen/Fogh study cannot be used to support Basic Research's advertising claims because Akävar contains additional ingredients than just the Herbal Compound, and those other ingredients may cancel the appetite suppressing effects derived from the Herbal Compound. Dr. Blonz particularly notes that Akävar contains ginger, which may increase appetite rather than suppress it, and that "the ginger included in Akävar is a concentrated plant extract." Blonz Rpt, at 20 (Dkt. No. 65). While Akävar does contain ginger, it is not from a concentrated plant extract. Instead, it is merely ginger root powder. Price Decl., ¶ 6 (Dkt. No. 118). Moreover, the studies Dr. Blonz relies on only show ginger may increase appetite when using a dose twelve times greater than that used in Akävar. Another study using a dose ten times greater showed no such effect. Toubro Second Supp. Decl., ¶ 22 (Dkt. No. 119). When drawing his conclusions, Dr. Blonz failed to address the dosage differences not only across studies but also in comparison to the amount in Akävar.

Dr. Blonz further opines that the Andersen/Fogh study does not support that the Herbal Compound would work on obese subjects since the study had no obese participants. Again, Dr.

Blonz misstates the study. In the 45-day weight loss protocol, study participants "had a BMI range of 25.8 to 30.4." *Id.* ¶ 26. This means the participants "ranged from moderately overweight to slightly obese" according to the National Institute of Health ("NIH") guidelines. *Id.* & n.16.[6] Consequently, this is an additional incorrect premise upon which Dr. Blonz bases his opinion about Akävar.

Relacore Background and FTC Challenges

The FTC also contends that Basic Research violated the Agreement by making false statements about Relacore in its advertising. Relacore is a dietary supplement that purportedly helps to reduce stress related belly fat. Complaint, ¶ 80 (Dkt. No. 1). The FTC contends that Basic Research made the following claims about Relacore and that such claims are not supported by competent and reliable scientific evidence:

> [1] Relacore reduces stress-induced abdominal fat more than diet and exercise alone; and
>
> [2] Relacore reduces abdominal fat in persons who are dieting and exercising but are retaining abdominal fat because of the stress of dieting.

On December 10, 2004, Basic Research obtained a declaration from Joel R.L. Ehrenkranz, M.D. Dr. Ehrenkranz is a board certified endocrinologist with "over twenty years experience in the clinical and research investigation of adrenal function and cortisol physiology." Declaration of Joel R.L. Ehrenkranz, M.D., ¶¶ 1–2 (Dkt. No. 88, Astrup Disc. Ex. 2-2). He is "familiar with the

[6] Although a BMI of 30.0 and above is recognized as obese in the United States, the Andersen/Fogh referred to its test subjects as being "mild moderate overweight (BMI range 25.8–30.4)." Andersen/Fogh Study, at 246 (Dkt. No. 88, Toubro Disc. Ex. 5-1). It did not state they were obese. This, however, does not negate the NIH's stated guidelines.

published scientific literature regarding the ingredients in Relacore™ and their effects on the endocrine and nervous systems." *Id.* ¶ 8. Relying on "over 100 scientific articles and studies which have been published in numerous medical books and journals, " *id.* ¶ 18, Dr. Ehrenkranz concluded the following advertising claims for Relacore were substantiated:

> [1] Stress increases cortisol;
>
> [2] A stress induced rise in cortisol increases visceral (belly) fat;
>
> [3] The active ingredients in Relacore have been shown to reduce stress and blunt stress induced cortisol production and action;
>
> [4] Cortisol reduction combined with diet and exercise will produce more visceral (belly) fat loss than diet and exercise alone; and
>
> [5] Diet and exercise in conjunction with a reduction of stress-induced cortisol will facilitate visceral (belly) fat loss.

Id. ¶ 9.

In 2007, Basic Research obtained an affidavit from Sten Madsbad, M.D. Dr. Madsbad is "an expert in the area of nutrition, obesity, diabetes, endocrinology and metabolism," which includes "over 20 years experience in clinical and metabolic investigations in adrenal function, and stress hormone physiology." Affidavit of Sten Madsbad, M.D., ¶ 5–6 (Feb. 7. 2007) (Dkt. No. 88, Astrup Disc. Ex. 2-4) (hereinafter "Madsbad Aff."). Relying on the same studies that Dr. Ehrenkranz reviewed in 2004, Dr. Madsbad attested "there is solid scientific evidence to support that Relacore reduce[s] stress, and the accompanying stress hormone levels." *Id.* ¶ 26. Dr. Madsbad further concluded "it is likely that these effects jointly will contribute to reduce abdominal obesity." *Id.*

Basic Research then obtained a third written opinion on May 11, 2009, this time from Arne V. Astrup, M.D. *See* Expert Report of Dr. Arne V. Astrup, ¶ 25 (undated) (Dkt. No. 88, Astrup Disc.

Ex. 2-5). Dr. Astrup is "an internationally recognized authority on obesity and the various medical conditions associated with obesity, and [has] . . . expertise in the related areas of weight loss." Declaration of Arne V. Astrup, ¶¶ 2–3 (Sept. 6, 2012) (Dkt. No. 88, Ex. A) (hereinafter "Astrup Decl."). Additionally he has "over 25 years of experience in clinical research conducted in accordance with Good Clinical Practice . . . with special emphasis on the etiology and treatment of obesity." *Id.* When forming his 2009 opinion, Dr. Astrup reviewed Dr. Madsbad's affidavit and opined that the affidavit standing alone "easily satisfied the scientific substantiation standard" contained in the Agreement. Expert Report of Dr. Arne V. Astrup, ¶¶ 25–26 (undated) in the case *Hopkins v. Basic Research, LLC*, Case No. 6:10-cv-01627-GAP-GJK) (M.D. Fla.) (Dkt. No. 88, Astrup Disc. 2-5).

Later, Dr. Astrup independently evaluated the scientific literature and stated in a report:

> The association between mental stress and abdominal obesity is so robust, and the plausibility of a causal relationship so well established, that it has become a widely accepted scientific proposition plainly stated in leading obesity textbooks. . . . Indeed, a systematic search of the relevant literature revealed no credible research that speaks against the established causal relationship between mental stress and abdominal obesity.

Id. ¶ 31. Dr. Astrup further explained that "the causal relationship between stress and abdominal obesity has become so widely recognized in the scientific community that many obesity researchers now recommend that various forms of stress management be employed as part of any successful weight loss regimen." *Id.* ¶ 36.

Dr. Astrup also reviewed three additional published, double-blind, placebo-controlled clinical trials and explained at length how the findings from those trials supported "the stress-reducing effect of Relacore," which stress reduction has "been directly correlated to improved weight loss efforts

[and] reduced abdominal adiposity" in other studies. *Id.* ¶ 64. Thus, Dr. Astrup opined that Basic Research's advertising "claims are amply supported by competent and reliable scientific evidence." *Id.* ¶ 66.

The FTC asserts, again through Dr. Blonz, that the above evidence is insufficient to show Basic Research has competent and reliable scientific evidence to support its advertising claims. Dr. Blonz evaluated Basic Research's evidence based on the following proposition:

> For the purpose of substantiating a claim that Relacore can bring about a reduction of abdominal fat, any evidence that Relacore, or an equivalent intake of its component ingredients, can bring about a reduction in stress must also report a statistically significant reduction in the level of cortisol or the level of abdominal fat in the body.

Blonz Rpt., ¶ 53 (Dkt. No. 65). Dr. Blonz explained:

> To constitute competent and reliable scientific evidence that the active ingredients in [R]elacore blunt stress-induced cortisol production, and/or reduce abdominal fat, an acceptable study would be one done with healthy individuals that examined effects using one or more of the active ingredients in Relacore where one of the variables measured was the level of cortisol, or the level of abdominal fat in the body. If such as a [sic] study were found, the other components in Relacore would be evaluated to determine if any might counteract or otherwise influence that effect.

Id. ¶ 54. During his deposition, Dr. Blonz further explained that in reviewing the scientific literature, he "wanted to find a study that showed that the ingredients in Relacore, when taken as directed, being taken by an otherwise healthy individual, would give rise to a decrease in the level of cortisol in the human body and/or a decrease in the level of visceral fat." Deposition of Edward R. Blonz, Ph.D., at 22:3–8 (Dkt. No. 88, Ex. D). Applying these premises, Dr. Blonz concluded:

> None of the studies cited [by Dr. Madsbad] provide competent and reliable evidence to support an effect of Relacore on the level of cortisol or the level of abdominal fat in humans. . . . Of the 61 studies

> cited, thirty-four (34) studies could not be considered because they had been done on animals or isolated cells, nine (9) studies could not be considered because their methodology did not involve any of the active ingredients found in Relacore. Seventeen (17) studies reported on elements of stress or mood involved ingredients found in Relacore, but they could not be considered because the methodology did not include any measure of an effect on cortisol or on the level of abdominal fat. . . . [T]here was one study that was done on humans, that examined effects from an active ingredient in Relacore, and that included a measure of an effect of the cortisol level. This study . . . involved a 100 milligram daily dose of DHEA given over a 6 month period. The study reported no change in the cortisol level.

Blonz Rpt., ¶ 55 (Dkt. No. 65). Moreover, Dr. Blonz conducted "his own search of the National Library of Medicine and the Natural Medicines Comprehensive Database" and concluded no studies substantiated Basic Research's advertising claims.

In a Supplemental Report, Dr. Blonz clarified that the scientific evidence does support the following three connections:

> [1] the ingredients in Relacore and their possible effect on certain measures of stress;
>
> [2] a cause-and-effect relationship between stress and the level of cortisol in the human body, and
>
> [3] a cause-and-effect relationship between the cortisol level and the amount [of] abdominal fat in the human body.

Blonz Supp. Rpt., ¶ 32 (Dkt. No. 99, Ex. 1). In other words, Dr. Blonz concurs "that there is a relationship between stress, cortisol and abdominal obesity," to such a degree that it "is not disputed and not at issue." *Id.* ¶ 44. But, while Relacore may reduce stress, Dr. Blonz concluded there is a lack of evidence to show Relacore reduces cortisol or abdominal fat in the *human body*. *Id.* Animal research, according to Dr. Blonz, is insufficient "to support a claimed effect in the human body." *Id.* ¶ 33.

In response to Dr. Blonz's report, Basic Research asked Dr. Astrup to provide a new report that applied the factors stated in the court's Order to determine whether Basic Research had a "reasonable basis" to make its claims about Relacore. Dr. Astrup's opinion did not change from that offered in his first report.

PROCEDURAL BACKGROUND

On May 23, 2011, the court issued a memorandum decision finding it had jurisdiction to interpret and define the scope of the Agreement. Subsequently, Basic Research moved for partial summary judgment on its First Claim for Relief. Under that claim, Basic Research sought for the court to declare its rights and obligations under the Agreement and to interpret the meaning of the "reasonable basis standard" set forth in the Agreement. The court granted the motion. *See* Order (Dkt. No. 69).

In so doing, the court held that the FTC is bound by the Agreement and may only seek to enforce it in accordance with the Agreement's terms. This means the FTC must follow the Agreement's definition of "competent and reliable scientific evidence" and not add to its terms. Additionally, the court held that once Basic Research proffers a basis it contends meets the requirements of the Agreement, the burden then shifts to the FTC to prove otherwise.

The court reserved ruling, however, on whether an alleged violation had to be proved by clear and convincing evidence or by a preponderance of evidence. The parties now seek to apply the court's ruling to the facts of this case through their respective summary judgment motions.

ANALYSIS

I. PROOF AND STANDARDS REQUIREMENTS

A. Burden of Proof

This case presents an unusual procedural posture because Basic Research instituted the lawsuit against the FTC. The FTC, however, did then file an enforcement action against Basic Research, which was consolidated into this action. Basic Research seeks declaratory judgment that it did not violate the terms of the parties' Agreement and the FTC seeks injunctive relief and civil penalties for Basic Research's alleged violation of the FTC's final order. The case is now in the third stage of litigation. In the first stage, the court held that it had jurisdiction to hear this case. In the second stage, the court interpreted the term's of the Agreement, which interpretation now governs these proceedings because both parties are bound by the Agreement. Having completed those two stages of litigation, the case is now at the "enforcement" stage where it must be determined whether Basic Research violated the terms of the Agreement.

When addressing jurisdiction, Basic Research represented to the court that it was not seeking to enjoin the FTC's enforcement action, extend its scope, or dismiss it. Instead, it was "seeking declaratory judgment about the legal meaning of the Agreement, which [could] then be applied to the facts at issue in the enforcement action." Mem. Dec. & Order, at 25 (May 23, 2011) (Dkt. No. 31). Because this case is now at that "enforcement" phase, the FTC carries the burden of proving that Basic Research violated the Agreement.

To meet this burden, the FTC must "establish a *prima facie* case" that Basic Research (1) "made claims or representations that fell within the terms of the [Agreement]", and (2) that Basic Research did not have a reasonable basis to make the claims or representations because it lacked competent and reliable scientific evidence. *See United States v. Alpine Indus., Inc.*, 77 Fed. Appx. 803, 808 (6th Cir. 2003) (setting forth the burden of proof). "[A] *prima facie* case is satisfied" when the FTC offers sufficient evidence to show that Basic Research had incompetent or unreliable

scientific evidence to support its claims or representations. *Id.* at 809. If the FTC meets its burden, the burden then shifts to Basic Research to show that it did have competent and reliable scientific evidence to support its claims or representations. *Id.* To the extent the court, in its June 1, 2012 Order, placed the initial burden on Basic Research to come forward with evidence during the enforcement stage, the court modifies its Order so that it follows the above requirements.

B. Standard of Proof

Having established who carries the initial burden of proof during the enforcement stage, the court must now address what standard of proof must be met. Basic Research contends the standard is clear and convincing. The FTC contends it is preponderance of the evidence. Based on the procedural posture of this case, the court concludes the FTC is correct.

Most cases applying the "clear and convincing" standard in FTC actions are contempt proceedings for violation of a court order. *See, e.g.*, *FTC v. Garden of Life, Inc.,* 845 F. Supp. 2d 1328 (S.D. Fla. 2012), *vacated in part & remanded in part on other grounds*, 516 Fed. Appx. 852 (11th Cir. 2013); *FTC v. Odysseus Mktg.*, No. 05-cv-330-SM, 2008 U.S. Dist. LEXIS 94213 (D.N.H. Sept. 30, 2008). Since civil contempt typically must be established by clear and convincing evidence, *FTC v. Kuykendall*, 371 F.3d 745, 754 (10th Cir. 2004), it is unremarkable that court's have applied that standard when the FTC has sought enforcement for a violation of a court order.

Applying a higher standard of proof is important, in part, because contempt proceedings have less due process protections. Indeed, "in civil contempt proceedings all that is required to satisfy the *Due Process Clause* is that defendants be given reasonable notice and an opportunity to be heard." *Id.* (citing *Int'l Union v. Bagwell*, 512 U.S. 821, 827 (1994)). This means a defendant is not entitled to a jury trial, and courts "may proceed in a more summary fashion than in an independent civil

action," including limiting the time for discovery and not allowing full pretrial motions to challenge the FTC's action. *See id.* at 754–56 (quotations and citation omitted).

This case does not resemble a contempt proceeding even though the FTC is seeking to enforce the Agreement as part of this litigation. The Agreement, itself, resulted from settlement negotiations between the parties. The proceeding was non-adjudicatory.[7] Thus, no court or administrative body entered findings of fact or conclusions of law following an evidentiary hearing or trial. Rather, the Agreement expressly provides that "said [A]greement is for settlement purposes only and does not constitute an admission . . . that the law has been violated as alleged [in the] Complaint." Agreement, at 2 (Dkt. No. 1, Ex. A). Moreover, the Agreement was never incorporated into a final *court* order. Additionally, the parties have had a full opportunity to present meaningful pretrial motions, two of which are at issue in this decision. Finally, Basic Research has made a jury demand (*see* Dkt. No. 48), which is the antithesis of a contempt proceeding that is held before a judge. *Kuykendall*, 371 F.3d at 754.

In *Alpine Industries*, the FTC brought an enforcement action for alleged violation of an FTC consent order. *Alpine Indus.*, 77 Fed. Appx. at 806. As in this case, the FTC sought civil penalties and injunctive relief. *Id.* During a jury trial, the jury was instructed that the standard of proof was preponderance of the evidence. *Id.* at 813. The Sixth Circuit accepted this standard when the case was appealed and it reviewed the jury instructions and special verdict form on a related issue.[8] *Id.*

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[7] Initially, the FTC proceeded in an adjudicatory proceeding, but later withdrew the matter when the settlement negotiations were successful. Agreement, at 2 (Dkt. No. 1, Ex. A). Under such circumstances, the proceeding is deemed to be non-adjudicatory. *See* 16 C.F.R. § 3.25(e).

[8] The Sixth Circuit reviewed the jury instructions and special verdict form to determine whether the trial court properly allocated the burden of proof to the government, but the jury instruction also instructed that the standard of proof was "preponderance of the evidence." That part of the instruction was not challenged.

Other courts likewise have applied the "preponderance of the evidence" standard when the FTC has sought civil penalties for an alleged violation of an FTC order. *See e.g.*, *FTC v. Lukens Steel Co.*, 454 F. Supp. 1182, 1200 (D.D.C. 1978) (applying preponderance of the evidence standard during a bench trial where the FTC sought civil penalties under 15 U.S.C. § 45(*l*) for alleged violation of a cease and desist order); *United States v. Louisiana-Pacific Corp*., 554 F. Supp. 504, 509 (D. Or. 1982), *rev'd on other grounds*, 754 F.2d 1445 (9th Cir. 1985) (applying preponderance of the evidence standard during a bench trial for alleged violation of a consent order). The court finds the proceedings in this case are most akin to those in *Alpine Industries*. Accordingly, it concludes the appropriate standard of proof is preponderance of the evidence.

C. Standard for Summary Judgment

"Summary judgment should be rendered if the pleadings, the discovery and disclosure material on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law." *Sabourin v. Univ. of Utah*, 676 F.3d 950, 957 (10th Cir. 2012) (quotations and citation omitted); *see also* Fed. R. Civ. P. 56(a). "A material fact is one that might affect the outcome of the suit under the governing law, and a genuine issue is one for which the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Pelt v. Utah*, 539 F.3d 1271, 1280 (10th Cir. 2008) (internal quotations and citations omitted). The court views evidence "in the light most favorable to the non-moving party." *Sabourin*, 676 F.3d at 957 (quotations and citation omitted).

II. COMPETENT AND RELIABLE SCIENTIFIC EVIDENCE

A. Provisions of the Agreement

The specific language of the Agreement states that at the time Basic Research makes an

advertising claim, Basic Research must "possess and rely upon a reasonable basis for the representation, which shall consist of competent and reliable scientific evidence." Agreement, at 5 (Dkt. No. 1, Ex. A). The Agreement defines "competent and reliable scientific evidence" as:

> tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.

Id. at 4. In its June 2012 Order, the court held that the language of the Agreement was clear and unambiguous and that Basic Research satisfies the terms of the Agreement when each of the following elements are met:

> [1] At the time a representation is made, there is a causal connection between the evidence proffered as support and the representation;
>
> [2] The representation is supported by competent and reliable scientific evidence which means evidence, including without limitation tests, analysis, research and studies, that:
>
> [a] is based upon the expertise of professionals in the relevant area;
>
> [b] conducted and evaluated in an objective manner;
>
> [c] by a person qualified to do so; and
>
> [d] uses procedures generally accepted in the profession to yield accurate and reliable results.

Order, ¶ 5 (Dkt. No. 69). In its enforcement action, the FTC must show that Basic Research's proffered support fails to meet one or more of these requirements.

B. Disagreement Among the Experts

As discussed above, the FTC's expert, Dr. Blonz, disagrees with the expert opinions offered

by Basic Research that it has competent and reliable scientific evidence to support its advertising claims. Typically, this would preclude summary judgment for either party because the differing opinions address material issues that are at the heart of this case.

"Unanimity of opinion in the scientific community, on virtually any scientific question, [however,] is extremely rare. Only slightly less rare is a strong majority." *United States v. Williams*, 583 F.2d 1194, 1198 (2d Cir. 1978); *see also* Toubro Second Supp. Decl., ¶ 7 (Dkt. No. 119) (stating "there is rarely certainty and complete consensus about anything" in the scientific community). Consequently, the Agreement "does not require [Basic Research] to only make representations that are supported by uncontroverted evidence." *Garden of Life, Inc.*, 845 F. Supp. 2d at 1337. Instead, it "merely requires [Basic Research] to possess competent and reliable evidence that substantiates its claims." *Id.* Thus, as stated in the Court's June 2012 Order, the FTC must do more than present an expert who simply disagrees with the scientific literature upon which Basic Research relied. The FTC must present evidence that shows how Basic Research's evidence fails to meet one of the above elements.

C. Rule 702 Requirements

The requirements of Rule 702 of the Federal Rules of Evidence must also be satisfied when a party offers an expert opinion. Rule 702 specifies that if an expert's opinion "will assist the trier of fact to understand the evidence or to determine a fact in issue," that expert may testify "if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case." Fed. R. Evid. 702.

The Rules of Evidence have a "liberal thrust," *Daubert v. Merrell Dow Pharm., Inc.*, 509

U.S. 579, 588 (1993), such that there is a "strong and undeniable preference for admitting any evidence having some potential for assisting the trier of fact." *United States v. Velasquez*, 64 F.3d 844, 849 (3d Cir. 1995) (quotation marks and citation omitted). Nevertheless, the court still retains a gatekeeper role to ensure that "expert testimony is both reliable and relevant" before it is admitted. *United States v. Rodriguez-Felix*, 450 F.3d 1117, 1122 (10th Cir. 2006) (citing Fed. R. Evid. 702). When determining whether an expert opinion is reliable, the court "must assess the reasoning and methodology underlying the expert's opinion." *Id.* at 1123 (quotation marks and citations omitted).

III. DR. BLONZ'S OPINIONS

A. Akavar

To support its claims for Akavar, Basic Research relies on the Andersen/Fogh study. It also relies on other studies and opinions of experts in the field. Dr. Blonz, however, only focused on the Andersen/Fogh study rather than looking at the totality of Basic Research's evidence. Moreover, Dr. Blonz stated he applied certain scientific assumptions in his report, which included measuring the evidence against the "ideal" or Gold Standard. Nowhere in the Agreement, nor in the court's June 2012 Order, does it state that Basic Research only has a reasonable basis when its proof consists of studies performed under the Gold Standard.

Although the Agreement states that "tests, analyses, research, studies, or other evidence" must use "procedures generally accepted in the profession to yield accurate and reliable results," the FTC has failed to show that the only procedures accepted in the profession are those that meet the ideal or the Gold Standard. Indeed, by characterizing a procedure as "ideal," it contemplates that other procedures may be adequate and accepted in the profession as well. Basic Research's experts confirm that while the Gold Standard may be ideal, it is not the only evidence accepted in the

profession as yielding accurate and reliable results. The Andersen/Fogh study itself also shows this point. The fourth module was not a double-blind, placebo controlled study. Yet, it still yielded publishable results and Dr. Blonz acknowledged "the competency and reliability of the [Andersen/Fogh] study as published research." Blonz Supp. Rpt., at 5 (Dkt. No. 99, Ex. 1). The court therefore concludes that Dr. Blonz failed to apply the correct standard when evaluating Basic Research's evidence.

Ironically, however, the third module of the Andersen/Fogh study does meet the Gold Standard. Thus, even though Dr. Blonz only accepted "ideal" studies, Basic Research provided such a study. Nevertheless, Dr. Blonz opines that the study does not correlate to the claims Basic Research made. Dr. Blonz based his opinion on inaccurate and incomplete facts. In particular, Dr. Blonz stated the dosage instructions for Akävar were different than those used in the Andersen/Fogh study. "Dose response refers to correlations between dosage and outcome." *In re Zoloft (Sertraline Hydrocloride) Prods. Liab. Litig.*, MDL No. 2342, 12-md-2342, 2014 U.S. Dist. LEXIS 111063, at *28 (E.D. Pa. Aug. 12, 2014). Different dosages may elicit different outcomes. The undisputed evidence shows, however, that the dosage instructions for Akävar were the same as those in the Andersen/Fogh study at least since June 2008. Dr. Blonz did not account for this in his opinion.

Next, when opining that Akävar may have a different effect than the Herbal Compound because it includes ginger, Dr. Blonz incorrectly stated Akävar contains a ginger extract rather than ginger root. This implicates the concentration of the ingredient. Two studies have shown that ginger in high concentrations may increase appetite. Yet, Dr. Blonz simply ignored the dosage of ginger in Akävar when opining Basic Research lacked competent evidence because its product contains ginger and ginger may increase appetite. No study proffered by the FTC shows ginger increasing

appetite at the dosage amount in Akävar. Thus, Dr. Blonz's opinion with respect to ginger is not supported by competent evidence.

Finally, Dr. Blonz stated that no correlation could be drawn between the Andersen/Fogh study and Akävar with respect to obese people because the study did not include test subjects who were obese. Yet, the study did include test subjects with a BMI of 30.4, which is considered to be obese.

By applying the incorrect standard Dr. Blonz's opinion lacks relevancy because he is opining that Basic Research's evidence does not meet the standard he has put forth, which is not the relevant standard. Moreover, by using incorrect facts on material issues, Dr. Blonz's opinion lacks reliability. The court therefore concludes the FTC has failed to make a *prima facie* showing that Basic Research lacks competent and reliable scientific evidence to substantiate its advertising claims with respect to Akävar. In contrast, Basic Research has provided reliable evidence that Basic Research's advertising claims for Akävar are supported by competent and reliable scientific evidence. Accordingly, the court grants summary judgment in favor of Basic Research with respect to Akävar.

B. Relacore

With respect to Relacore, Dr. Blonz does not dispute that the ingredients in Relacore have been shown to reduce stress. He also does not dispute that there is a cause-and-effect relationship between stress and the level of cortisol in the human body. Nor does he dispute there is a cause-and-effect relationship between the cortisol level and the amount of abdominal fat in the human body. He nevertheless opines that Basic Research lacks competent and reliable scientific evidence that Relacore (1) Relacore reduces stress-induced abdominal fat more than diet and exercise alone; and (2) Relacore reduces abdominal fat in persons who are dieting and exercising but are retaining

abdominal fat because of the stress of dieting.

To support these claims, Dr. Blonz opines that an "acceptable study" would be one where a human test subject takes one or more of the active ingredients in Relacore and the effects on the level of cortisol and abdominal fat are then measured. Unless a study contains all of these components, it cannot support Basic Research's claims according to Dr. Blonz. Because no such study exists, Dr. Blonz asserts Basic Research lacks competent and reliable scientific evidence. Again, Dr. Blonz failed to apply the correct standard. While competent and reliable scientific evidence may consist of a single study under certain circumstances, the Agreement does not require that every aspect of an advertising claim be contained in one study. Nor does it preclude drawing inferences and correlations between different studies.

For Dr. Blonz to state 34 studies cited by Dr. Madsbad and Dr. Astrup could not be considered because they were done on animals or isolated cells is unsound and does not evidence that his opinion is the product of reliable principles and methods. *See* Fed. R. Evid. 702. "[A]nimal studies play an important role in human medical research." *Rosen v. Ciba-Geigy Corp*., 78 F.3d 316, 319 (7th Cir. 1996). While "an automatic extrapolation from [animals] to human beings would not be warranted," *id.*, summarily disregarding such studies, as Dr. Blonz does, also is not warranted. *See In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 781 (3d Cir. 1994) (holding district court erred when it summarily excluded animal studies); *see also FDA Guidance for Indus. Nonclinical Safety Eval. of Pediatric Drug Prods.*, 2006 WL 841810 (F.D.A. Feb. 2006) (discussing "some conditions under which juvenile animals can be meaningful predictors of toxicity in pediatric patients"); Supplemental Expert Declaration of Dr. Arne V. Astrup, ¶ 14 (Dkt. No. 117) (hereinafter "Astrup Supp. Decl.") (stating it is "appropriate to consider all available tests, *animal data*, human

experimental and observational studies and other scientific evidence to determine whether there is evidence to support a particular conclusion or claim" (emphasis added)).

Dr. Blonz summarily disregarded the other studies as well because they did not contain all factors within one study. For example, Dr. Blonz disregarded one study because it was "an in vitro assay studying receptor binding; it provide[d] no evidence regarding the effects of the active ingredients of Relicore [sic] *in humans* and it involved no measure of cortisol level." Blonz Rpt., Attach. X, ¶ 1(s) (Dkt. No. 65-24) (emphasis added). Yet, another study that did examine anxiety in humans and an active ingredient in Relacore was disregarded because it "did not involve any measure of cortisol." *Id.* ¶ 1(t). A further study looked at the relationship between cortisol levels in humans who were exposed to acute stress. Although the study was relevant to study the cause-effect relationship between stress and cortisol, Dr. Blonz disregarded it because the study did not examine "[t]he active ingredients in the Relicore [sic] product." *Id.* ¶ 1(zz).

Nowhere in Dr. Blonz's report does he make an attempt to explain why correlations and inferences cannot be drawn across these reports. He simply looked to see if a study had every relevant factor and if it did not, he disregarded it, even though "reasonable scientific inferences and extrapolation are methodologies regularly used and relied upon by experts in the field." Astrup Supp. Decl., ¶ 15. Dr. Blonz's standard imposes "higher criteria than are commonly expected in scientific research," such that Basic Research's expert, Dr. Astrup, found "Dr. Blonz's conclusion that 'there is an absence of evidence in the scientific literature to substantiate [the alleged claims]'" to be "quite startling." Astrup Decl., ¶ 40 (Dkt. No. 88, Ex. A).

The FTC plays an important role of ensuring that advertising claims are adequately supported so that consumers may have confidence in a product. Implicit in that role, however, is the

expectation of reasonableness. Here, the approach taken by the FTC through its expert requires a level of substantiation that exceeds the requirements of the Agreement and the court's June 2012 Order. Because Dr. Blonz failed to apply the proper standard when evaluating the efficacy of the studies presented by Basic Research, his opinion about Relacore is not relevant or reliable. The court therefore concludes the FTC has failed to make a *prima facie* showing that Basic Research lacks competent and reliable scientific evidence to substantiate its advertising claims with respect to Relacore. In contrast, Basic Research has provided reliable evidence that Basic Research's advertising claims for Relacore are supported by competent and reliable scientific evidence. Accordingly, the court grants summary judgment in favor of Basic Research with respect to Relacore.

V. FTC'S THIRD CAUSE OF ACTION

Basic Research further moves for summary judgment on the Third Cause of Action asserted by the FTC in its Complaint.[9] The FTC asserts the Andersen/Fogh study "does not prove the claims for Akävar. . . . Defendants therefore misrepresented the validity of this clinical study as well as the manner in which it should be interpreted, thereby violating Part III of the Order." FTC Complaint, ¶ 20 (Dkt. No. 2 in case 2:09-cv-972). Part III of the Agreement states Basic Research "shall not misrepresent, in any manner, expressly or by implication, . . . the existence, contents, validity, results, conclusions, or interpretations of any test, study, or research." Agreement, at 5 (Dkt. No. 1, Ex. A).

The validity of the Andersen/Fogh study is beyond dispute; both parties have acknowledged

[9] The FTC's case, 2:09-cv-972, was consolidated into the present case pursuant to local rule DUCivR 42-1.

it is competent and reliable scientific evidence. Additionally, after analysis of the study, Dr. Toubro concluded "Basic Research has not misrepresented the validity of the Andersen/Fogh study." Toubro Second Supp. Decl., ¶ 30 (Dkt. No. 119). Consequently, Basic Research did not make any false representation as to its validity. With respect to "the manner in which it should be interpreted," the FTC has not shown how that condition is contemplated in the language of the Agreement. The Agreement states Basic Research may not misrepresent interpretations of the Andersen/Fogh study. That is a different concept than the one articulated by the FTC in its Complaint. Moreover, when Basic Research expressly moved for summary judgment on this claim, the FTC did not oppose it in its opposition memorandum. For these reasons the court grants summary judgment in favor of Basic Research on the FTC's Third Cause of Action.

DATED this 25th day of November, 2014.

BY THE COURT:

Clark Waddoups
United States District Court